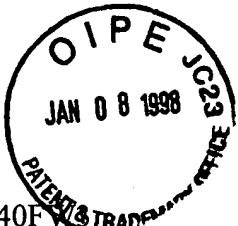


CVDINC.040F



*JL*  
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Paul G. Yock, et al.	)	Reissue of U.S. 4,887,606
Serial No.	:	08/904,438	)	Group Art Unit 3305
Filed	:	July 31, 1997	)	
Patent No.	:	4,887,606	)	
Issued	:	December 19, 1989	)	
For	:	APPARATUS FOR USE IN CANNULATION OF BLOOD VESSELS	)	

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SUPPLEMENTAL COMBINED POWER OF ATTORNEY  
AND DECLARATION OF ALAN R. SELFRIDGE

Assistant Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

I, Alan R. Selfridge, declare as follows:

1. I am an original and a joint inventor in the above-described original U.S. Patent No. 4,887,606 ('606 patent) and the application for the reissue thereof.
2. I have reviewed and understand the contents of the specification, including the claims of the original patent U.S. Patent No. 4,887,606 ('606 patent).
3. I acknowledge the duty to disclose information which is material to the examination of this reissue application in accordance with 37 C.F.R. § 1.56(a).

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**Filed** : July 31, 1997

4. I believe the original '606 patent to be partly inoperative or invalid because of errors without deceptive intent on the part of the applicants, by reason of the fact that we claimed less than we had the right to claim in the original patent. The specific errors included:

- a. The term "trocar" was used in the specification when the correct term should have been "stylet."
- b. A brief description of Figs. 5-7 was not given in the original application.
- c. In Col. 3, line 18 of the '606 patent, "this" should have been "the" and "shown in Fig. 5" should have been included after "embodiment."
- d. In Col. 3, line 36 of the '606 patent, "PZTSA" should have been "PZT5A."
- e. In Col. 3, lines 46 and 47 of the '606 patent, "container portion" was used when the correct term should have been "syringe."
- f. Claim 1 of the '606 patent was unduly limiting in that it called for a support rod for supporting the transducer and means to attach the transducer to the support rod. As generally described in the specification, the transducer secures to the end of a transducer insert, i.e., the stylet, not necessarily to a support rod which was the specific embodiment shown in the drawings.
- g. In Claim 1 of the '606 patent, the metal conductor and the support rod were required to be spaced from the needle to facilitate back flow of blood. However, the specification clearly states that it is the stylet which is spaced from the needle. Additionally, the structure and organization of Claim 1 of the '606 patent made

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**Filed** : July 31, 1997

it unclear whether the support rod was to be part of the stylet or an entirely separate element.

h. In Claim 1 of the '606 patent, the stylet was required to be positioned within the needle but the needle was not required to have an inner lumen into which the stylet was to be positioned.

i. In Claim 3 of the '606 patent, the term "rod" was used when the correct term should have been "stylet" to thereby correspond to the "stylet" in amended Claim 1 from which Claim 3 depends.

j. In Claim 6 of the '606 patent, reference was made to a "trocar" when the correct term should have been "stylet."

k. In Claim 6 of the '060 patent, "into" was used when the correct term should have been "to" which more particularly defines and distinctly claims the structural relationship in the subject matter which I regard as the invention.

l. In regard to new Claims 7, in addition to the errors identified in Paragraphs 4(f)-(h) in relation to Claim 1 of the '606 patent, Claim 1 was unduly limiting in that it called for a syringe portion detachably attached to the needle. While the apparatus may be used in conjunction with a syringe, a syringe is not a necessary component of the apparatus which I regard as the invention.

m. In regard to new Claim 8, the structure of the stylet was described in the specification of the '606 patent, but was not claimed in conjunction with the features of new Claim 7.

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- n. In regard to new Claim 9, the circular ultrasound transducer means was described in the specification of the '606 patent, but was not claimed in conjunction with the features of new Claims 7 and 8.
- o. In regard to new Claim 10, the structure of the ultrasound transducer means was described in the specification of the '606 patent, but was not claimed in conjunction with the features of new Claims 7-9.
- p. In regard to new Claim 11, the relationship between the stylet and the hollow needle was described in the specification of the '606 patent, but was not claimed in conjunction with the features of new Claim 7. In addition, it was not clear from Claim 1 of the '606 patent whether the embodiment shown in Fig. 5 and described in Col. 3, lines 18-25 of the '606 patent was covered.
- q. In regard to new Claim 12, the stainless steel tubing forming the second conductor was described in the specification of the '606 patent, but was not claimed in conjunction with the features of new Claim 7.
- r. In regard to new Claim 13, the use of a syringe was described in the specification of the '606 patent, but was not claimed in conjunction with the features of new Claim 7.
- s. In regard to new Claims 14-15, the claimed method of using the apparatus was described in the specification of the '606 patent, but was not claimed or appreciated by the attorney handling the prosecution of the original application.

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- t. In regard to new Claim 16, in addition to the errors identified in Paragraphs 4(f)-(h) in relation to Claim 1 of the '606 patent, Claim 1 was unduly limiting in that it called for a syringe portion detachably attached to the needle. While the apparatus may be used in conjunction with a syringe, a syringe is not a necessary component of the apparatus which I regard as the invention.
- u. In regard to new Claim 17, the use of a syringe was described in the specification of the '606 patent, but was not claimed in conjunction with the features of new Claim 16.
- v. In regard to new Claim 18, the shape and position of the first and second conductors were described in the specification of the '606 patent, but were not claimed in conjunction with the features of new Claim 16.
- w. In regard to new Claim 19 which depends from amended Claim 1, the shape and position of the first and second conductors were described in the specification of the '606 patent, but were not claimed in conjunction with the features of amended Claim 1.
- x. In regard to new Claims 20-21,<sup>1</sup> Claim 4 of the '606 patent was unduly limiting in that it called for a support rod for supporting the transducer and means to attach the transducer to the support rod. As generally described in the specification, the transducer is secured to the end of a transducer insert, i.e., the

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<sup>1</sup> It is noted that original new Claim 22 was renumbered to Claim 21 by the Supplemental Amendment filed on September 2, 1993 in connection with parent application Serial No. 07,808,751 filed December 17, 1991.

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**Filed** : July 31, 1997

stylet, not necessarily to a support rod which was the specific embodiment shown in the drawings.

y. In regard to new Claim 22,<sup>2</sup> the claimed kit comprising a hollow needle and a stylet for use in the cannulation of a blood vessel was described in the specification of the '606 patent, but was not claimed or appreciated by the attorney handling the prosecution of the original application.

z. New Claim 23 was submitted with the Supplemental Amendment filed on September 2, 1993 in connection with application Serial No. 07,808,751 filed December 17, 1991, and is identical to the previously allowed Claim 1 of the '606 patent.

5. The attorney handling the prosecution of the original application, through error, without deceptive intent, failed to recognize the above-described features of the invention in their broadest sense and the aforesaid errors which had occurred in the specification and claims.

6. I am not sure how the aforesaid errors occurred, but I believe that they occurred during the preparation and prosecution of the application which issued as the original '606 patent.

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<sup>2</sup> It is noted that original new Claim 23 was renumbered to Claim 22 by the Supplemental Amendment filed on September 2, 1993 in connection with parent application Serial No. 07/808,751 filed December 17, 1991.

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**Filed** : July 31, 1997

7. After Advanced Cardiovascular Systems, Inc. (ACS) became the exclusive licensee under the '606 patent in 1990, ACS requested Edward J. Lynch, their counsel, to review the '606 patent.

8. As a result of Mr. Lynch's review, he concluded that the claims of the '606 patent were unduly narrow in certain respects and that certain errors had occurred in the specification, as set out in paragraph 4 above, and that the specification and claims should be corrected by means of a reissue application.

9. During the prosecution of the Japanese application corresponding to the '606 patent, a reference was cited which appeared to be pertinent to the claimed invention of the '606 patent but which had not been considered by the Examiner during the prosecution of the application which led to the '606 patent.

10. It has been recommended to me that this reference found by the Japanese Examiner be considered during the examination of a reissue application based upon the '606 patent.

11. I have reviewed the '606 patent and agree with the assessment that the claims thereof were too narrow and unduly limiting in certain respects, that other errors had occurred in the specification and claims which needed to be corrected, and that the pertinent reference found by the Examiner in the corresponding Japanese application should be considered by the U.S. Examiner in a reissue application.

12. I have reviewed the Preliminary Amendment filed on December 17, 1991, the Amendment filed on April 28, 1993, and the Supplemental Amendment filed on September 2,

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1993 containing amendments to Claims 1 and 6 of the '606 patent, additions of new Claims 7 to 23, and amendments to the specification. A copy of the Preliminary Amendment is attached hereto as Exhibit A, a copy of the Amendment is attached hereto as Exhibit B, and a copy of the Supplemental Amendment is attached hereto as Exhibit C.

13. I agree with the assessment that the amended and new claims provide greater protection to our invention than the original claims of the '606 patent. I also agree with the corrections to the specifications and claims made by the Preliminary Amendment, Amendment, and Supplemental Amendment.

As the below-named inventor of United States Patent Application 08/904,438 filed July 31, 1997 entitled APPARATUS FOR USE IN CANNULATION OF BLOOD VESSELS, I do hereby revoke any and all past powers of attorneys. Further, I hereby appoint Gerard von Hoffmann, Registration No. 33,043, and Steven J. Nataupsky, Registration No. 37,688, as my attorneys of record to prosecute this application and to transact all business in the Patent and Trademark Office connected herewith. Please address all correspondence and telephone calls to:

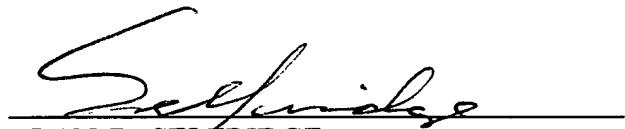
Steven J. Nataupsky  
Knobbe, Martens, Olson & Bear  
620 Newport Center Drive  
Sixteenth Floor  
Newport Beach, CA 92660  
(714) 760-0404

I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these

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statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful, false statements may jeopardize the validity of the application or patent issuing therefrom.

Dated: 11/22/97

  
\_\_\_\_\_  
ALAN R. SELFRIDGE

CWM-2434  
110797  
[CRL-1283:040996]

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the reissue application of ) Reissue of U.S. 4,887,606  
PAUL G. YOCK et al. ) Examiner  
For APPARATUS FOR USE IN ) Group Art Unit  
CANNULATION OF BLOOD VESSELS )  
Serial No. )  
Filed [Concurrently herewith] )  
Atty. Docket 18000.5003.3 )

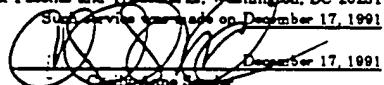
December 17, 1991

CROSBY, HEAFEEY, ROACH & MAY  
Los Angeles, California

CERTIFICATE OF MAILING UNDER 37 CFR 1.10

I hereby certify that this correspondence is being deposited with the  
United States Postal Service in an postage prepaid envelope as  
"Express Mail Post Office to Addressee" using  
Mailing Label No. DB 036 477 650

This correspondence is addressed to:  
Commissioner of Patents and Trademarks, Washington, DC 20231

Such service was made on December 17, 1991  
  
December 17, 1991  
John W. Sauer

PRELIMINARY AMENDMENT

The Commissioner  
United States Patent  
and Trademark Office  
Washington, DC 20231

Dear Sir:

Please preliminarily amend the above-identified application for  
the reissue of U.S. Patent 4,887,606 as follows:

IN THE SPECIFICATION

In column 2, line 2, and in column 3, lines 22 and 25 change "trocar" at

each occurrence to --stylet--.

In column 2, line 3, insert the following:

--FIG. 5 is a partial cross-sectional view of a needle and an alternative stylet.

FIGS. 6 and 7 are additional alternative embodiments of stylets in accordance with the invention..

In column 3, line 18, delete "this" and insert --the--, and after "embodiment" insert --shown in FIG. 5--.

In column 3, line 46, change "container portion" to --syringe-. and in line 47 change "container" to --syringe--.

#### IN THE CLAIMS

Please amend claim 1 as follows:

- 1        1. (Amended) Apparatus for use in cannulation of blood vessels
- 2        comprising

3           a hollow needle having an inner lumen, a sharpened distal end  
4        for penetrating tissue and a proximal end adapted to receive a syringe,  
5           a stylet having proximal and distal ends, being positioned within  
6       the inner lumen of said needle and being spaced from the interior of said  
7       needle to facilitate back flow of blood when a blood vessel is penetrated,  
8       the stylet including an ultrasound transducer supported at [one] the  
9       distal end for transmitting and receiving ultrasonic waves through the  
10      sharpened end of said needle,

11           [a support rod for supporting said transducer, means attaching  
12      said transducer to said support rod, coaxial] electrical conductors  
13      associated with said [support rod] stylet for transmitting electrical  
14      signals to and from said transducer, including a [wire] first conductor  
15      extending through said [support rod] stylet electrically connected with  
16      a back surface of said transducer, and a [metal] second conductor on the  
17      surface of said [rod] stylet electrically [interconnected] connected with a  
18      front surface of said transducer[, said metal conductor and support rod  
19      being spaced from said needle to facilitate back flow of blood when a  
20      blood vessel is penetrated], and  
21           a syringe portion detachably attached to the proximal end of said  
22      needle.

*1/4*  
In claim 6, line 1, change ftrocari] to --stylet--

Please add the following new claims:

1       7. Apparatus for use in cannulation of blood vessels comprising  
2       a hollow needle having an inner lumen, a sharpened distal end for  
3       penetrating tissue  
4       a stylet having proximal and distal ends, being positioned within the  
5       inner lumen of said needle, having an inner lumen to facilitate back  
6       flow of blood when the distal end of the needle is disposed within the  
7       blood vessel, the stylet including an ultrasound transducer means  
8       supported at the distal end of the stylet for transmitting and receiving  
9       ultrasonic waves through the sharpened end of said needle.

10      electrical conductors associated with said stylet for transmitting  
11      electrical signals to and from said transducer means, including a first  
12      conductor having a cylindrical shape and being electrically connected  
13      with a first surface of said transducer means, and a second conductor  
14      being electrically connected with a second surface of said transducer.

1       8. The apparatus of claim 7 wherein the stylet has an inner lumen  
2       extending longitudinally therein formed by the cylindrically shaped conductor  
3       and the ultrasound transducer means is secured to the end of the cylindrically  
4       shaped conductor.

1           9.    The apparatus of claim 8 wherein the ultrasound transducer  
2    means has a circular shape.

1           10.   The apparatus of claim 9 wherein the ultrasound transducer  
2    means has a central aperture which is in communication with the inner lumen  
3    of the stylet.

1           11.   The apparatus of claim 7 wherein the stylet is disposed within the  
2    inner lumen of the hollow needle with the second conductor electrically  
3    connected to the hollow needle.

1           12.   The stylet of claim 7 wherein the second conductor is stainless  
2    steel tubing.

1           13.   The stylet of claim 7 wherein a syringe is releasably secured to  
2    the proximal end of the needle.

1           14.   A method for guiding a hollow needle through tissue into a blood  
2    vessel of a patient comprising:

3           a)    providing an apparatus which includes:  
4                    a hollow needle having an inner lumen, a sharpened  
5                   distal end for penetrating tissue and a proximal end.

6                   an elongated stylet having proximal and distal ends  
7                   positioned within the inner lumen of said needle and  
8                   including an ultrasonic transducer means secured to the  
9                   distal end of the stylet for transmitting and receiving  
10                  ultrasonic waves through the sharpened distal end of said  
11                  needle having a front surface and a rear surface, electrical  
12                  conductors associated with said stylet for transmitting  
13                  electrical signals to and from said transducer means,  
14                  including a first electrical conductor extending through the  
15                  interior of the stylet and being electrically connected to one  
16                  surface of said transducer means, and a second electrical  
17                  conductor being electrically connected to a second surface  
18                  of said transducer means;

19                  b)    penetrating the skin of the patient with the sharp distal  
20                  end of the needle and advancing the needle through the tissue of the  
21                  patient;

22                  c)    emitting ultrasonic waves from the ultrasound transducer  
23                  means on the distal end of the stylet, receiving reflected ultrasonic  
24                  waves by said transducer means and generating a signal representing  
25                  the reflected ultrasonic waves; and

26                  d)    adjusting the direction of the distal sharpened end of the  
27                  needle as it is advanced through the patient's tissue based upon the

28       received ultrasonic waves to direct the sharpened distal end of the  
29       needle into a blood vessel of the patient, the approach of the needle to  
30       a blood vessel characterized by an increase in the intensity of the signals  
31       representing the reflected ultrasonic waves and the positioning of the  
32       sharpened distal end of the needle within a blood vessel characterized  
33       by a substantial increase in the signal representing the reflected  
34       ultrasonic waves.

1       15. The method of claim 14 wherein a syringe is secured to the  
2       proximal end of the needle and a back pressure is applied on the syringe to  
3       effect a negative pressure within the needle to create a back flow of blood into  
4       the syringe when the sharpened distal end of the needle is disposed within a  
5       blood vessel.

1       16. An apparatus for use in the cannulation of a blood vessel  
2       comprising:

3           a hollow needle having an inner lumen, a sharpened distal end  
4           for penetrating tissue and a proximal end, and  
5           a stylet having proximal and distal ends, being positioned within  
6           the inner lumen of said needle and being spaced from the interior of said  
7           needle to facilitate back flow of blood when the needle is positioned  
8           within a blood vessel, the stylet including an ultrasound transducer

9       means supported at the distal end of the stylet for transmitting and  
10      receiving ultrasonic waves through the sharpened end of said needle  
11      electrical conductors associated with said stylet for transmitting  
12      electrical signals to and from said transducer means, including a first  
13      conductor extending through said stylet electrically connected with a  
14      first surface of said transducer, and a second conductor disposed about  
15      the first conductor electrically connected with a second surface of said  
16      transducer means.

1           17. The apparatus of claim 16 wherein a syringe is releasably secured  
2       to the proximal end of the needle.

1           18. The apparatus of claim 16 wherein the first conductor has a  
2       cylindrical shape, is disposed about the second conductor and is connected to  
3       the front surface of the transducer means and the second conductor is  
4       connected to the back surface of the transducer means.

1           19. The apparatus of claim 1 wherein the first conductor has a  
2       cylindrical shape, is disposed about the second conductor and is connected to  
3       the front surface of the transducer means and the second conductor is  
4       connected to the back surface of the transducer means.

1           20. A stylet having proximal and distal ends adapted to positioned  
2       within an inner lumen of a needle and dimensioned to be spaced from the  
3       interior of said needle to facilitate back flow of blood when the needle is  
4       positioned within a blood vessel, the stylet comprising:

- 5           a)   an elongated body having proximal and distal ends;  
6           b)   an ultrasound transducer means supported at the distal end  
7       of the elongated body for transmitting and receiving ultrasonic waves  
8       through the sharpened end of said needle; and  
9           c)   electrical conductors associated with said stylet for  
10       transmitting electrical signals to and from said transducer means,  
11       including a first conductor wire extending through said stylet which is  
12       electrically connected with a rear surface of said transducer means, and  
13       a second conductor of essentially cylindrical shape disposed about the  
14       first conductor electrically connected with a front surface of said  
15       transducer means.

1           22. The stylet of claim 21 wherein solid insulation is disposed  
2       between the first and second conductors.

1           23. A kit for use in the cannulation of a blood vessel comprising:  
2           a)   a hollow needle having an inner lumen, a sharpened distal  
3       end for penetrating tissue and a proximal end; and

4           b)    a stylet having proximal and distal ends adapted to be  
5           positioned within the inner lumen of said needle and being spaced from  
6           the interior of said needle to facilitate back flow of blood when the  
7           needle is positioned within a blood vessel, the stylet including an  
8           ultrasound transducer means supported at the distal end of the stylet  
9           for transmitting and receiving ultrasonic waves through the sharpened  
10          end of said needle, electrical conductors associated with said stylet for  
11          transmitting electrical signals to and from said transducer means,  
12          including a first conductor extending through said stylet electrically  
13          connected with a first surface of said transducer, and a second conductor  
14          disposed about the first conductor electrically connected with a second  
15          surface of said transducer means.

#### REMARKS

The patentees respectfully request that the above amendments to the specification and the claims, including the addition of new claims, be considered by the Examiner during the initial examination of this application. It is believed that the amended and the new claims define patentable subject matter and consideration and an early allowance thereof are respectfully requested.

The applicants wish to bring to the attention of the Examiner a Japanese Patent Publication 48-30874 which was cited in the corresponding Japanese application after the U.S. Patent 4,887,606 issued. This reference may be pertinent to the present invention and was not considered by the U.S. Patent and Trademark Office during the examination of the original U.S. Patent 4,887,606. A copy of the Japanese Patent Publication and a translation thereof are attached hereto along with a listing thereof on PTO-1449.

Respectfully submitted,



Edward J. Lynch  
Registration No. 24,422  
Attorney for Applicant

Telephone: (213) 896-8006  
Facsimile: (213) 896-8080

700 South Flower Street, Suite 2200  
Los Angeles, CA 90017

63,952-009

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Yock et al

Serial No.: 07/808,751 Group Art Unit: 3305

Filed: 12/17/91 Examiner: F. Jaworski

For: APPARATUS FOR USE IN CANNULATION OF BLOOD VESSELS

Attorney Docket No.: 63,952-009

Commissioner of Patents & Trademarks  
Washington, D. C. 20231

AMENDMENT

Dear Sir:

In response to the Office Action of November 3, 1992, please amend the above-identified application as follows.

In the Specification:

In column 2, line 30, change "direct" to --directly--.

In column 3, line 19, change "trocar" to --stylet--.

In column 3, line 31, insert the following after "72.":

--Elements 74 and 75 are conductors and insulative portions, respectively, and are used analogously to such elements in the previous figures.--

In the Claims:

Please amend claim 3 as follows:

3. (Amended) Apparatus as defined by claim 1 wherein said means attaching said transducer to said [rod] stylet includes an ultrasound damping material.

Please amend claim 6 as follows:

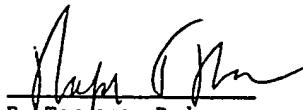
6. (Amended) The stylet as defined by claim 4 wherein said means attaching said transducer [into] to said rod includes an ultrasound damping material.

REMARKS

The patentees respectfully request reconsideration by the Examiner with respect to the initial examination of this application since the claims clearly define patentable subject matter. Each of the claims require that the transducer transmit and receive ultrasonic waves through the sharpened end of a needle. The Northeved reference states that the piezoelectric element at the end of the stiletto receives ultrasonic energy while the piezoelectric element in the housing 10 emits ultrasonic energy. Neither the Northeved nor Omizo references teach or make obvious the claimed construction of a stylet being positioned within the inner lumen of a needle and being spaced from the interior of the needle to facilitate backflow of blood when a blood vessel is penetrated with the stylet including an ultrasound transducer supported at its distal end for both transmitting and receiving ultrasonic waves through the sharpened end of the needle. Further, the cited references fail to teach or make obvious a conductor extending through the stylet and connected with a back surface of the transducer and another conductor on the surface of the stylet connected with a front surface of the transducer. Thus, the cited references fail to teach or make obvious the claimed combination of elements or their functional relationship.

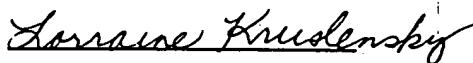
The Examiner's rejection based upon an insufficient reissue declaration is not understood since the declaration does point out how the alleged errors arose or occurred as required by 37 C.F.R. 1.175. If the Examiner intends to maintain this rejection, the patentees respectfully request an opportunity to discuss the bases for any such rejection in further detail so that an appropriately revised declaration may be submitted to obviate the Examiner's objections. It is believed, however, that the declaration is proper and that the claims define patentable subject matter, and reconsideration and an allowance thereof are respectfully requested.

Respectfully submitted,

  
R. Terrence Rader  
Registration No. 28,772  
DYKEMA GOSSETT  
400 Renaissance Center  
Detroit, Michigan 48243  
(313) 540-0863  
Attorneys for Applicants

CERTIFICATE OF MAILING

I hereby certify that the enclosed Amendment is being deposited with the United States Postal Service as "Post Office to Addressee" Express Mail, Receipt No. IB222043844, postage prepaid, in an envelope addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20231, on this 28th day of April, 1993.



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Yock, et al.

Serial No.: 07/808,751 Group Art Unit: 3305

Filed: 12/17/91 Examiner: Jaworski

For: APPARATUS FOR USE IN CANNULATION OF BLOOD  
VESSELS

Attorney Docket No.: 63,952-009

Commissioner of Patents and Trademarks  
Washington, D.C. 20231

SUPPLEMENTAL AMENDMENT

Dear Sir:

In response to the Office Actions of November 3, 1992, and July 27, 1993, the telephone interview of August 18, 1993, and the personal interview of August 26, 1993, please amend the above-identified application as follows.

Please add the following new claim:

--23. Apparatus for use in cannulation of blood vessels comprising:

a hollow needle having a sharpened end for penetrating tissue,

a stylet positioned within said needle and including an ultrasound transducer at one end for transmitting and receiving ultrasonic waves through the sharpened end of said needle,

a support rod for supporting said transducer,

means attaching said transducer to said support rod, coaxial electrical conductors associated with said support rod for transmitting electrical signals to and from said transducer, including a wire extending through said support rod electrically connected with a back surface of said transducer, and a metal conductor on the surface of said rod electrically interconnected with a front surface of said transducer, said metal conductor and support rod being spaced from said needle to facilitate back flow of blood when a blood vessel is penetrated, and

a syringe portion detachably attached to said needle.--

REMARKS

Applicants' representative thanks the Examiner for the telephone interview on August 18, 1993, and for the personal interview on Thursday, August 26, 1993.

As a preliminary matter, Applicants wish to confirm that all further communications in this application should be sent to R. Terrance Rader at the address identified at the end of this response, in accordance with the Combined Power of Attorney and Declaration of Alan R. Selfridge dated May 26, 1992 and Paul G. Yock dated May 1, 1992. The Office Actions of November 3, 1992 and July 27, 1993 as well as the Interview Summary from the telephone interview of August 18, 1993, were sent to the prior counsel involved in the prosecution of this reissue application. Correction of the Patent Office records to reflect the correct power of attorney would be appreciated.

Pursuant to the telephone interview of August 18, 1993, agreement was reached that the Examiner would amend the application so that original claim 22 would be renumbered to claim 21; original claim 23 would be renumbered to claim 22; the dependency of original claim 22 (now claim 21) would be changed

to claim 20; and original claim 23 (now claim 22) would remain independent.

Pursuant to the personal interview on Thursday, August 26, 1993, agreement was reached that claims (1-22) are patentable over the prior art of record. Newly added claim 23 is original claim 1 of Applicant's U.S. Patent No. 4,887,606, and therefore, it is believed to be allowable as well. Thus, the only remaining matter to be addressed is the Examiner's request for a further explanation as to why the Reissue Declaration is acceptable as filed.

The Reissue Declaration was objected to for failing to comply with 37 CFR 1.175 (a)(3) and (a)(5). First, the Declaration was objected to for failing to specifically point out how the errors arose or occurred with respect to the specification and the claims. In paragraphs 4 and 5 of the Declarations of Yock and Selfridge, the Applicants state that the "attorney handling the prosecution of the original application, through error, without deceptive intent, failed to recognize the above described features of the invention in their broadest sense and the aforesaid errors which had occurred in the specification and claims." Thus, the errors arose or occurred because of a failure by prior counsel to recognize features of the invention in their broadest sense. Since Applicants were not personally responsible for the errors, the most Applicants could say in paragraph 6 of their respective Declarations was that they believed that the errors occurred during the preparation and prosecution of the application.

The Declaration was also objected to for failing to specifically pointing out how the errors in claims 7-22 arose, including any excess or insufficiency. In response, Applicants note that claims 7-22 were not part of the claims of the issued patent. 37 CFR 1.175 addresses errors, including distinctly

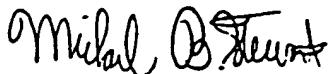
specifying the excess or insufficiency for the claims in the issued patent, not claims that are added through the reissue process. Therefore, there are no errors with respect to claims 7-22 that the Declaration should address. The Declaration does distinctly specify any excess or insufficiency with respect to claims 1 and 6 of the issued patent as well as the fact that the method of using the apparatus described in the specification was not claimed. The Declarations of Yock and Selfridge also state sufficient facts as to how and when the excess or insufficiency arose.

Therefore, Applicants respectfully submit that the Reissue Declaration complies with the requirements of 37 CFR 1.175 and ask that it be entered by the Examiner.

Finally, as set forth above, Applicants submit new claim 23 which corresponds to claim 1 of the '606 patent. Claim 1 was amended in the preliminary amendment without including a claim with the same limitations as the previously allowed claim 1. It is respectfully submitted that this claim is allowable over the prior art of record.

In view of these supplemental remarks, it is believed that claims 1-23 are allowable and that the Reissue Declaration meets the requirements of 37 CFR 1.175. An early indication of such is respectfully solicited. If the Examiner has any questions, he is asked to contact the undersigned.

Respectfully submitted,



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CERTIFICATE OF MAILING

I hereby certify that the enclosed Supplemental Amendment is being deposited with the United States Postal Service as Express Mail, "Post Office to Addressee", Label No. IB222044757, postage prepaid, in an envelope addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20231, on this 2nd day of September, 1993.

Stephanie A. Fash

MBST/1221